

What's New in the Guidelines? (Updated September 14, 2011)

Key changes made to update the May 24, 2010, version of the guidelines are summarized below. Throughout the revised guidelines, significant updates are highlighted and discussed.

- **Lessons Learned from Clinical Trials of Antiretroviral Interventions to Reduce Perinatal Transmission and Table 3 (Results of Major Studies on Antiretroviral Prophylaxis to Prevent Mother-to-Child Transmission of HIV):**
 - This section and [Table 3](#) include updates on recent results from international clinical trials, including HPTN 046 in breastfeeding infants, which demonstrated that extending infant nevirapine prophylaxis from 6 weeks to 6 months improved efficacy in reducing postnatal infections, and NICHD-HPTN 040/PACTG 1043 in formula-feeding infants, which demonstrated that when mothers have not received antepartum antiretroviral (ARV) drugs, combination infant ARV prophylaxis reduces intrapartum transmission more than the standard 6-week infant zidovudine regimen.
- **Preconception Care and Table 4 (Drug Interactions Between Hormonal Contraceptives and Antiretroviral Agents):**
 - This section includes a new subsection on [Reproductive Options for HIV Concordant and Serodiscordant Couples](#). The subsection includes discussion of HPTN 052 trial in discordant couples, which demonstrated that initiating antiretroviral therapy (ART) in infected individuals with CD4 cell counts from 350 to 550 cells/mm³ reduced the risk of transmission to seronegative partners. The subsection also includes discussion on trials of pre-exposure ARV prophylaxis.
 - The section includes a new Table ([Table 4](#)) on drug interactions between hormonal contraceptives and ARV drugs.
- **Recommendations for Use of Antiretroviral Drugs during Pregnancy and Table 5 (Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy):**
 - [Table 5](#) on ARV drugs in pregnancy has been revised to include drug formulation and dosing information in addition to pregnancy-related pharmacokinetic and toxicity data and recommendations for use in pregnancy. [Table 5](#) also includes the newly approved drug rilpivirine.
 - There is expanded discussion on treatment recommendations for adults and postpartum discontinuation of ARV drug regimens.
 - Tenofovir has moved from a nucleoside reverse transcriptase inhibitor (NRTI) for *Use in Special Considerations* to an *Alternative* NRTI choice; it is the *Preferred* NRTI choice for women who are co-infected with HIV and hepatitis B virus.
 - Indinavir and nelfinavir have moved from *Alternative* protease inhibitor (PI) choices to PIs to *Use in Special Circumstances*.
- **HIV-Infected Pregnant Women Who Have Never Received Antiretroviral Drugs (Antiretroviral Naïve):** This section includes expanded discussion of new data suggesting early and sustained control of HIV viral replication is associated with decreased transmission in women who have undetectable viral load at delivery—data which favors initiation of ARV drugs as early in pregnancy as possible for all women.

- **HIV/Hepatitis B Coinfection:** The Panel now recommends combination ARV drug regimens including anti-hepatitis B drugs for all HIV-infected pregnant women with hepatitis B virus (HBV) coinfection:
 - All pregnant women with HIV/HBV coinfection should receive a combination ARV drug regimen, including a dual nucleoside reverse transcriptase inhibitor (NRTI)/nucleotide analogue reverse transcriptase inhibitor (NtRTI) backbone with two drugs active against both HIV and HBV (**AII**). Tenofovir plus lamivudine or emtricitabine is the preferred dual NRTI/NtRTI backbone of a combination antepartum ARV regimen in HIV/HBV-coinfected pregnant women (**AI**).
- **Acute HIV Infection:** This is a new section discussing diagnosis and management of acute HIV-1 infection in pregnancy.
- **HIV-2 Infection and Pregnancy:** This is a new section discussing diagnosis and management of HIV-2 infection in pregnancy.
- **Combination Antiretroviral Drugs and Pregnancy Outcome:** Data from several new studies on preterm delivery and combination ARV drug regimens are reviewed in this section. The Panel notes the following:
 - Clinicians should be aware of a possible small increased risk of preterm birth in pregnant women receiving PI-based combination ARV regimens; however, given the clear benefits of such regimens for both the women's health and the prevention of mother-to-child transmission, PIs should not be withheld for fear of altering pregnancy outcome (**AII**).
- **Intrapartum Antiretroviral Therapy/Prophylaxis:** Based on the results of the NICHD-HPTN 040/P1043 clinical trial, the Panel's no longer recommends intrapartum single-dose nevirapine for HIV-infected women in labor who have not received antepartum drugs. In this circumstance, the Panel recommends the following:
 - Intravenous zidovudine is recommended for HIV-infected women in labor who have not received antepartum ARV drugs, and infant combination ARV prophylaxis is recommended for 6 weeks (see [Infant Antiretroviral Prophylaxis](#)) (**AII**).
- **Postpartum Care:** This section includes expanded discussion of considerations regarding stopping ARVs postpartum, including discussion of results of HPTN 052 and of the importance of counseling on safer sex practices and contraception during the postpartum period.
- **Infant Antiretroviral Prophylaxis and Table 9 (Intrapartum Maternal and Neonatal Dosing for Additional Antiretroviral Drugs in Special Circumstances Based on NICHD-HPTN 040/PACTG 1043 Regimen):**
 - The Panel now recommends that twice daily dosing can be used for the 6-week zidovudine prophylaxis regimen in full-term infants.
 - The recommended dose of zidovudine for post-exposure prophylaxis in full-term neonates is 4 mg/kg body weight orally twice daily for the first 6 weeks of life, beginning as soon after birth as possible and preferably within 6–12 hours of delivery.
 - The design and results of the NICHD-HPTN 040/PACTG 1043 clinical trial in formula-fed infants are discussed. The trial demonstrated that when mothers have not received antepartum ARV drugs, combination infant ARV prophylaxis reduces intrapartum transmission more than the standard 6-week infant zidovudine regimen. Based on these data, the Panel's recommendation is now:

- Infants born to HIV-infected women who have not received antepartum ARV drugs should receive prophylaxis with a combination ARV drug regimen, started as soon after birth as possible (AI). A randomized, controlled trial has shown that a 2-drug regimen of zidovudine given for 6 weeks combined with three doses of nevirapine in the first week of life (at birth, 48 hours later, and 96 hours after the second dose) is as effective as but less toxic than a 3-drug regimen of zidovudine, nelfinavir and lamivudine. The 2-drug regimen is preferred due to lower toxicity and because nelfinavir powder is no longer available in the United States. (see [General Considerations for Choice of Infant Prophylaxis](#) and [Table 9](#)) (AI).
- [Table 9](#) includes the dosing for the 2-drug regimen used in the NICHD-HPTN 040/PACTG 1043 trial.
- A new subsection is included on management of breastfeeding infants of mothers first diagnosed with HIV infection during the postpartum period.
- Discussion on revised guidance for use of lopinavir/ritonavir in neonates is provided. Lopinavir/ritonavir should not be administered to neonates before a postmenstrual age (first day of the mother's last menstrual period to birth plus the time elapsed since birth) of 42 weeks and a postnatal age of at least 14 days.